REMARKS

This Amendment is in response to the Office Action mailed March 4, 2003, which sets a three-month period for response. Reconsideration and withdrawal of the objections to and rejections of this application are respectfully requested in view of this amendment and remarks herewith.

Claims 1 to 12 are pending in this application and claims 1, 2, 3, 4, 5, 7 and 12 are amended. Claims 13 to 16 are canceled without prejudice, due to non-elected subject matter. Applicant reserves the rights to pursue canceled subject matter in a continuation application.

Applicant disagrees with the objections and rejections made in the March 4, 2003 Office Action, however, in the interest of expediting prosecution of this patent application, claims 1, 2, 3, 4, 5, 7 and 12 are amended.

Support for the amended recitation in claims 1, 2, 3, 4, 5, 7 and 12 can be found in the originally filed specification.

No new matter is added.

It is submitted that these claims, as originally presented, are patentably distinct over the references cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. Changes to these claims and the addition of the new claims, as presented herein, are not made for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112. Rather, these changes and additions are made simply for clarification and to round out the scope of protection to which Applicant is entitled.

Applicant re-affirms his election of Group III invention directed to claims 2 and 3 with traverse and thanks the Examiner for rejoining Groups II, III and IV claims for further

prosecution of this application. Claims 13 to 16 are withdrawn from consideration pursuant to 37 C.F.R. §1.142(b), as being drawn to non-elected subject matter.

Reconsideration and withdrawal of the objections to and rejections of this application and consideration and entry of this paper are respectfully requested in view of the amendments and remarks herein, which place the application in condition for allowance.

Claims 1, 3 to 6 and 13 are objected to due to certain informalities. (Office Action, at 3). The Examiner is thanked for her helpful suggestions.

In view of the claim amendments herewith, reconsideration and withdrawal of the objections are respectfully requested.

Claim 5 is rejected under 35 USC §112, paragraph 2, as said to be indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. (Office Action, at 4).

In view of the amendment of claim 5, Applicant submits that the rejection is moot, and respectfully urges reconsideration and withdrawal of this rejection.

Claim 1 is rejected under 35 USC §102(a) as allegedly being anticipated by Bruchfeld et al. (Journal of the American Society of Nephrology, September, 2000, Vol. 11, No. Program and Abstract Issue, pp. 57A.) ("Bruchfeld"). (Office Action, at 4 to 5). Claim 1 is also rejected under 35 USC §102(b) as allegedly being anticipated by Weisz et al. (IDS#BW, Paper No. 4) ("Weisz"). (Office Action, at 5). These rejections will be collectively addressed.

The present invention teaches and discloses a new use for erythropoietin, such as EPO alpha, in treating ribavirin-interferon-alpha induced anemia. More specifically, the present invention can be administered to humans as well as animals infected with Hepatitis C virus or HIV or HIV and HCV or who are suffering from anemia. Accordingly, the invention teaches

using EPO with hepatitis C treatment, such as Ribavirin ("RBV") and/or interferon such as alpha-interferon ("α-IFN" or "IFN"); and thus, the invention pertains to methods involving administration of EPO, RBV and α-IFN, or EPO and RBV, and compositions and kits containing EPO, RBV and α-IFN or EPO and RBV. The Erythropoetin can be administered in a liquid preparation and/or administered as a vector for *in vivo* expression. Specifically, the present invention also evaluates the clinical benefit of erythropoietin in ribavirin/interferon-induced anemia.

Bruchfeld relates to using ribavirin to treat dialysis and renal insufficient patients with HCV. In the abstract of Bruchfeld, it specifically stated that "...ribavirin is contraindicated in renal insufficiency due to fear of side-effects." (*Bruchfeld*, lines 10 to 11). Bruchfeld does not teach the combination therapy of using EPO with RBV to control the anemic condition of patients since by so doing, Bruchfeld believes would result in side-effects for the dialysis and renal insufficient patients. Therefore, Bruchfeld teaches away from the present invention in that it specifically discourages the use of ribavirin in any combination therapy.

Weisz relates to a treatment for HIV positive patients having HCV.

"For a prior art reference to anticipate in terms of 35 U.S.C. 102(a), every element of the claimed invention must be identically shown in a single reference." *Scripps Clinic & Research Foundation v. Genetech, Inc.*, 18 U.S.P.Q.2d 1001 (Fed. Cir. 1991). Bruchfeld does not claim and disclose a method of using EPO to treat a hepatitis C patient and/or an anemic condition resulting from a ribavirin and interferon-alpha combined treatment in HCV patients since Bruchfeld teaches away from using RBV all together. Weisz does not teach using EPO to treat a hepatitis C patient who is HIV negative.

Since neither Bruchfeld nor Weisz disclose or suggest every element of the presently claimed invention, the 35 U.S.C. §§102(a) and 102(b) rejections based on Bruchfeld and/or Weisz cannot stand.

Reconsideration and withdrawal of the rejections to claim 1 under 35 U.S.C. §§102(a) and 102(b) based on Bruchfeld and Weisz are respectfully requested.

Claims 2-5 and 7-11 are rejected under 35 USC §103(a) as said to be unpatentable over Bruchfeld in view of Niitsu et al., US Patent No. 6,268,336 ("Niitsu"). (Office Action, at 6 to 7). Claim 12 is rejected under 35 USC §103(a) as said to be unpatentable over Weisz in view of Niitsu. (Office Action, at 7 to 8).

Niitsu relates to a pharmaceutical composition for treatment of hepatic diseases. However, Niitsu, as the Office Action correctly pointed out: "...does not teach the administration of RBV, IFN and EPO in patients co-infected with HCV and HIV." (Office Action, at 7).

Since neither Bruchfeld nor Niitsu disclose using Erythropoetin such as EPO alpha, to treat hepatitis C and/or anemic condition resulted from a hepatitis C treatment, the 35 U.S.C. 103(a) rejections based on Bruchfeld and/or Niitsu either alone or in combination cannot stand.

By the same token, since neither Weisz nor Niitsu disclose using Erythropoetin such as EPO alpha, to treat hepatitis C and/or anemic condition resulted from a hepatitis C treatment, the 35 U.S.C. 103(a) rejections based on Weisz and/or Niitsu either alone or in combination cannot stand.

In an obviousness rejection, the standard established in *In re Fritch*, 23 U.S.P.Q.2d 1780, 1783-84 (Fed. Cir. 1992), must be followed. *Fritch* in pertinent part states (with emphasis added):

> Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under Section 103, teachings of references can be combined only if there is some suggestion or incentive to do so . . . . **The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.**

Even if a reference can be modified in a way that the Examiner suggests, this does not mean that the reference renders the instant invention obvious unless the motivation to make the modification suggested by the Examiner is in the reference's teaching. It is respectfully submitted that no such teaching exists in the references cited by the current Office Action either alone or in any combination. There is nothing in the references' teachings suggesting the modification or the desirability of the modification. There is no evidence in the Office Action showing why a skilled artisan would have combined the cited references and then would have arrived at the present invention.

There must be some teaching, suggestion, or incentive in the references (and not Applicant's disclosure) that supports the combination of the references. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599-1600 (Fed. Cir. 1988). No such teaching, suggestion or incentive is in the cited documents.

According to the Board of Patent Appeals and Interferences in the case of *Ex parte Obukowicz*, 27 U.S.P.Q.2d 1063, 1065 (B.P.A.I. 1992) (with emphasis added):

> In proceedings before the Patent and Trademark Office, the Examiner bear the burden of establishing a *prima facie* case of obviousness based upon the prior art. *In re Piasecki*, 745 F.2d 1468, 1471-72, 223 U.S.P.Q. 785, 787-88 (Fed. Cir. 1984). **The Examiner can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references**. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d

> 1596, 1598 (Fed. Cir. 1988). **Indeed, the teachings of references can be combined only if there is some suggestion or incentive to do so.** *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 723 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984).

The picking and choosing from both of the cited references to allege that the instant invention is obvious simply fails in light of the case law under Section 103. The Examiner is respectfully invited to cite references for the desirability of modification and the teaching, suggestion or incentive for combination and for modification of the reference teachings or provide an affidavit, as called for by 37 C.F.R. §1.106(b) and M.P.E.P. §706.02(a). Otherwise, it is respectfully submitted that the Section 103 rejection must be withdrawn.

Accordingly, none of cited references, alone, or in any combination, render Applicant's invention *prima facie* obvious. Moreover, none of the references teach or suggest the surprising properties of the presently claimed invention, as shown in the application, which properties, Applicant submits are additionally demonstrative of the patentability of the instant invention.

Consequently, the present invention is not anticipated nor obvious in view of Bruchfeld, Weisz and Niitsu, either alone or in any combination since these references either alone or in any combination fail to supply the deficiencies that are claimed and disclosed in the present invention.

Applicant therefore respectfully requests that the rejections to claims 2 to 5 and 7 to 11 based on Bruchfeld either alone or in combination with Niitsu and claim 12 based on Weisz either alone or in combination with Niitsu under 35 U.S.C. §103(a) be withdrawn.

In view of these amendments and remarks, Applicant respectfully submits that all of the claims (claims 1 to 12) now pending in the application are in condition for allowance.

If any issue remains as an impediment to allowance, an interview with the Examiner is respectfully requested, prior to issuance of any paper other than a Notice of Allowance; and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

In view of the amendments and remarks herewith, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance, or an interview at an early date with a view to placing the application in condition for allowance, are earnestly solicited.

Any additional fee occasioned by this paper or the claims herein, or any overpayment therein, may be charged or credited to Deposit Account No. 50-0320.

Respectfully submitted,

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